UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

RICHARD EIDSON, Plaintiff, v. MEDTRONIC, INC.; MEDTRONIC SOFAMOR DANEK USA, INC., Defendants.	Case Nos.: 13-CV-02049-LHK 13-CV-01502-LHK ORDER GRANTING DEFENDANTS' MOTION TO DISMISS SCOTT AND APRIL BELL'S COMPLAINT, AND GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS RICHARD EIDSON'S COMPLAINT
SCOTT BELL AND APRIL BELL, Plaintiffs, v. MEDTRONIC, INC.; MEDTRONIC SOFAMOR DANEK USA, INC., Defendants.	

Plaintiffs Scott and April Bell bring this action based on harmful side effects Scott Bell suffered after undergoing spinal surgery in which his surgeon used a medical device produced by Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Defendants"). ECF Bell

No. 1 at 1 ("Bell Complaint").[1] Plaintiff Richard Eidson also brings this action based on harmful side effects he suffered after undergoing spinal surgery in which his surgeon used the same product produced by Defendants. ECF Eidson No. 1 at 1("Eidson Complaint"). The two cases have been related because they involve the same product and similar questions of law. ECF Bell No. 23. Defendants move to dismiss both complaints pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted. ECF Bell No. 10; ECF Eidson No. 9. This order addresses both motions to dismiss. Having considered the submissions of the parties, the relevant law, and the record in this case, the Court GRANTS IN PART AND DENIES IN PART Defendants' motion to dismiss Richard Eidson's complaint, and GRANTS Defendants' motion to dismiss Scott and April Bell's complaint without prejudice.

I. BACKGROUND

A. Factual Allegations

1. Infuse Device

Medtronic Sofamor Danek, USA, Inc. manufactures a medical device known as the Infuse Device which stimulates bone growth, obviating the necessity of harvesting bone from a patient's hip.[1] Bell Complaint ¶¶ 2, 51; Eidson Complaint ¶¶ 2, 50. Doctors can use the Infuse Device in spinal fusion surgeries to form a bone graft. *Id*. ¶¶ 1-2; *Id*. ¶¶ 1-2. The Device consists of three components: (1) a metallic spinal fusion cage (the LT Cage), (2) the bone graft substitute, which consists of liquid rhBMP–2, and (3) a spongy carrier or scaffold for the protein that resides in the fusion cage. *Id.* ¶ 34; *Id*. ¶ 33. The latter two components are collectively called the Infuse Bone Graft. *Id.* ¶ 58; *Id.* ¶ 57. During surgery, the doctor attaches the fusion cage to the diseased spinal region in order to stabilize the area, soaks the collagen sponge with the rhBMP–2, and applies it to the diseased region. *Id*. ¶¶ 35-36; *Id.* ¶¶ 34-35. Later, the sponge dissolves while the rhBMP–2 stimulates the spinal cells to grow new bone in place of the diseased area. *Id.*; *Id.*

[1] As this case is related to another case brought by a different plaintiff against the same defendant and this order addresses both cases, this order will utilize the following terminology for docket numbers in the *Bell* case: "ECF Bell No. X," and the following terminology for docket numbers in the *Eidson* case: "ECF Eidson No. X."

2. Premarket Approval of the Infuse Device

The Infuse Device is a Class III device under the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"). *Id.* ¶¶ 45, 54; *Id.* ¶¶ 44, 54. Class three devices are those that pose the greatest risk of death or complications. *Id*; *Id*. Defendants were required to obtain premarket approval ("PMA") from the FDA before they could sell the Infuse Device. *Id.* ¶¶ 44, 46; *Id.* ¶¶ 43, 45.

In July 2002, the FDA granted the Infuse Device PMA for spinal fusion procedures. *Id.* ¶¶ 4, 56-57; *Id.* ¶¶ 4, 55-56. The FDA's approval letter stated that the Device may be implanted (1) from the anterior (front) abdomen, and (2) placed within lumbar spine levels L4 through S1. *Id.* ¶ 59; *Id.* ¶ 58. The FDA-approved labeling stated that the Infuse Bone Graft must not be used without the LT Cage. *Id.* ¶ 58; *Id.* ¶ 57. Any operation that uses the Infuse Device in a manner other than that which has been approved by the FDA is called an "off-label" use. *Id.* ¶¶ 60, 62. This includes posterior lumbar interbody fusion surgery ("PILF") (approaching the spine from the back), posterolateral fusion surgery (also approaching the spine from the back), or surgeries without the LT Cage. *Id.* ¶¶ 4, 59, 62; *Id.* ¶¶ 4, 58, 61. As described below, Plaintiffs' claims stem from off-label uses of the device. *Id.* ¶¶ 1-3, 279; *Id.* ¶¶ 1-3, 278.

In 2011, off-label uses of the Infuse Device made up close to ninety percent of the $800 million dollars in revenue the Device generated for Defendants. *Id.* ¶ 110; *Id.* ¶ 109. Defendants spent large sums of money to promote off-label uses by establishing consulting/royalty agreements with physicians who advocated off-label uses. *Id.* ¶¶ 112-114, 118-119; *Id.* ¶¶ 111-113, 117-118. Yet Defendants knew that various studies showed that off-label use could produce severe side effects in patients. *Id.* ¶¶ 64-73, 96-97; *Id.* ¶¶ 63-64, 95-96. Specifically, PLIF surgery had resulted in excessive bone growth in the location where the bone protein component of the device was applied. *Id.* ¶¶ 64-65; *Id.* ¶¶ 63-64.

Defendants tried to suppress this information by funding studies that omitted mentions of risk and funding articles by opinion leaders that showed a lower incidence of off-label adverse effects. *Id.* ¶¶ 80, 98, 119-120, 172-177; *Id.* ¶¶ 79, 97, 118-119, 171-176. In addition, Defendants

failed to report certain adverse events to the FDA. *Id.* ¶¶ 106, 129-132, 165, 278; *Id.* ¶¶ 105, 128-131, 164, 277. These activities led to investigations by the Department of Justice and to significant controversial media coverage in the *Wall Street Journal* and the *New York Times.* *Id.* ¶¶ 89, 115, 133-135, 148, 178, 185, 195; *Id.* ¶¶ 88, 114, 132-34, 147, 177, 184, 194.

3. Plaintiff Scott Bell's Surgery

In February 2005, Scott Bell underwent a decompression laminectomy and posterolateral fusion surgery. Bell Complaint ¶ 279. His physician used the Infuse Device in an off-label manner by implanting it by means of a posterior, not anterior, approach, and an LT Cage was not used. *Id.*

Bell alleges Defendants directly and indirectly encouraged his surgeon to use an off-label procedure. *Id.* ¶ 280. After the surgery, Bell was diagnosed with bony overgrowth and underwent corrective surgery, whereby his surgeon discovered large columns of extra bone. *Id.* ¶ 281. He now has severe bony overgrowth, debilitating leg pain, decreased sensation, weakness, and other injuries presently undiagnosed. *Id.* ¶ 282.

As a result, Plaintiffs Scott and April Bell brought six causes of action against Defendants in connection with the Infuse Device: (1) fraudulent misrepresentation and fraudulent inducement (*Id.* ¶¶ 284-296); (2) strict products liability—failure to warn (*id.* ¶¶ 297-310); (3) strict products liability—design defect (*id.* ¶¶ 311-320); (4) strict products liability—misrepresentation (*id.* ¶¶ 321-329); (5) products liability—negligence (*id.* ¶¶ 330-340); (6) products liability negligence for loss of consortium on behalf of April Bell (*id.* ¶¶ 341-343).

4. Plaintiff Richard Eidson's surgery

In November 2008, Plaintiff Richard Eidson underwent an L3-L4 and L2-3 multilevel posterior lumbar interbody fusion and posterolateral fusion surgery. Eidson Complaint ¶ 278. His physician performed the surgery in an off-label manner by implanting the Infuse Device by means of a posterior, not anterior, approach, by using a multi-level fusion, and an LT Cage was not used. *Id.*

Eidson alleges Defendants directly and indirectly encouraged his surgeon to use an off-label procedure. *Id.* ¶ 279. After the surgery, he began experiencing new pain in his back and bilateral

legs, experienced onset of new leg weakness, decreased leg sensation, and decreased reflexes in his legs. *Id.* ¶ 280. He was diagnosed with fluid-filled cysts within the vertebral bodies where the surgery had taken place. *Id.* Eidson now has severe low back pain, buttock pain, bilateral leg pain, and reduced sensation, strength, and reflexes in his lower extremities. *Id.* ¶ 281. He has also suffered bone resorption and ectopic bone growth, or bone overgrowth. *Id.* ¶ 12, 73.

As a result, Eidson brought five causes of action against Defendants in connection with the Infuse Device: (1) fraudulent misrepresentation and fraudulent inducement (*Id.* ¶¶ 283-95); (2) strict products liability—failure to warn (*id.* ¶¶ 296-309); (3) strict products liability—design defect (*id.* ¶¶ 310-319); (4) strict products liability—misrepresentation (*id.* ¶¶ 320-328); and (5) products liability—negligence (*id.* ¶¶ 329-339).

B. Procedural History

Plaintiffs Scott and April Bell filed their complaint on April 3, 2013. ECF Bell No. 1. Defendants filed a Motion to Dismiss the Complaint on May 14, 2013. ECF Bell No. 10 ("Bell MTD"). Plaintiffs filed an opposition to the Motion to Dismiss on July 1, 2013. ECF Bell No. 20 ("Bell MTD Opp"). Defendants filed a reply on July 22, 2013. ECF Bell No. 24.

Plaintiff Richard Eidson filed his complaint on May 6, 2013. ECF Eidson No. 1. Defendants filed a Motion to Dismiss the Complaint on May 28, 2013. ECF Eidson No. 9 ("Eidson MTD"). Plaintiff filed an opposition to the Motion to Dismiss on July 1, 2013. ECF Edison No. 18 ("Edison MTD Opp"). Defendants filed a reply on July 22, 2013. ECF Eidson No. 21. On August 21, 2013, Plaintiffs and Defendants filed separate notices of supplemental authorities. ECF Bell Nos. 29, 30; ECF Eidson Nos. 24, 25. On September 6, 2013, Plaintiffs filed a notice of supplemental authorities. ECF Bell No. 31; ECF Eidson No. 26. On September 27, 2013, Defendants filed a statement of recent decisions. ECF Bell No. 33; ECF Eidson No. 28. The Court has considered these supplemental authorities. The Court also reminds the parties that Local Rule 7.3(d)(2) prohibits argument in such notices and statements.

II. LEGAL STANDARDS

A. Motion to Dismiss Under Rule 12(b)(6)

Rule 8(a)(2) of the Federal Rules of Civil Procedure requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." A complaint that fails to meet this standard may be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6). The Supreme Court has held that Rule 8(a) requires a plaintiff to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (internal quotation marks omitted). For purposes of ruling on a Rule 12(b)(6) motion, a court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008).

However, a court need not accept as true allegations contradicted by judicially noticeable facts, *Shwarz v. United States*, 234 F.3d 428, 435 (9th Cir. 2000), and the "court may look beyond the plaintiff's complaint to matters of public record" without converting the Rule 12(b)(6) motion into one for summary judgment, *Shaw v. Hahn*, 56 F.3d 1128, 1129 n.1 (9th Cir. 1995). Nor is the court required to "'assume the truth of legal conclusions merely because they are cast in the form of factual allegations.'" *Fayer v. Vaughn*, 649 F.3d 1061, 1064 (9th Cir. 2011) (per curiam) (quoting *W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981)). Mere "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss." *Adams v. Johnson*, 355 F.3d 1179, 1183 (9th Cir. 2004); *accord Iqbal*, 556 U.S. at 678.

B. Federal Rule of Civil Procedure 9(b)

Claims for fraud must overcome the heightened pleading requirements of Rule 9(b). Fed. R. Civ. P. 9(b). Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." *Id.* A complaint must "be 'specific enough to give defendants notice of the particular misconduct . . . so that they can defend against

the charge and not just deny that they have done anything wrong.'" *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (citation omitted). The complaint must include an account of the "time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1066 (9th Cir. 2004) (citation omitted). In addition, "[t]he plaintiff must set forth what is false or misleading about a statement, and why it is false." *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc), *superceded by statute on other grounds.* A plaintiff must also plead "the statements made and by whom made, an explanation of why or how such statements were false or misleading when made, and the role of each defendant in the alleged fraud." *Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1090 (C.D. Cal. 2011).

C. Leave to Amend

If the Court determines that a complaint should be dismissed, it must then decide whether to grant leave to amend. Under Rule 15(a) of the Federal Rules of Civil Procedure, leave to amend "should be freely granted when justice so requires," bearing in mind that "the underlying purpose of Rule 15 . . . [is] to facilitate decision on the merits, rather than on the pleadings or technicalities." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (internal quotation marks omitted). Nonetheless, a court "may exercise its discretion to deny leave to amend due to 'undue delay, bad faith or dilatory motive on part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party. . . , [and] futility of amendment.'" *Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 892-93 (9th Cir. 2010) (alterations in original) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

D. Requests for Judicial Notice

Federal Rule of Evidence 201(d) provides that "[a] court shall take judicial notice [of an adjudicative fact] if requested by a party and supplied with the necessary information." Fed. R. Civ. P. 201(d). An adjudicative fact is subject to judicial notice when the fact is "not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the

trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot be reasonably questioned." *Id.*

III. ANALYSIS

Defendants argue that Scott and April Bell's claims are expressly preempted by the MDA, 21 U.S.C. § 360k(a), as interpreted by the Supreme Court in *Riegel v. Medtronic*, 552 U.S. 312 (2008), because they seek to impose state law requirements on the design, manufacture, or labeling of the Infuse Device that are different from or in addition to the federal requirements imposed by the FDA. They also argue that to the extent their claims seek to enforce the provisions of federal law governing the promotion of medical devices for "off-label" uses, they are impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Defendants further argue that all of the claims are barred by the statute of limitations, that the strict liability design defect claim is barred by the Restatement Second of Torts, that the fraud claims are not pled with the requisite particularity, and that April Bell's loss of consortium claim is derivative and thus fails along with the claims upon which it depends. Bell MTD at 15-21. The Bells concede that their strict liability design defect claim is barred by the Restatement Second of Torts, but argue that the rest of their claims are not preempted and that their claims are pled with the requisite particularity.

Similarly, Defendants argue that Richard Eidson's claims are expressly and impliedly preempted, that his strict liability design defect claim is barred by the Restatement Second of Torts, and that his fraud claims are not pled with the requisite particularity. Eidson MTD at 16-17. Eidson concedes that his strict liability design defect claim is barred by the Restatement Second, but argues that the rest of his claims are not preempted and are pled with the requisite particularity.

Before addressing these arguments, the Court first addresses the parties' requests for judicial notice and the legal framework.

A. Requests for Judicial Notice

Defendants filed Requests for Judicial Notice in support of their motions to dismiss. ECF Bell No. 11; ECF Edison No. 10. The documents constitute: (i) the FDA PMA database listing for the Infuse device approving the device for spinal fusion procedures; (ii) the FDA's PMA letter for

the Infuse device approving the device for spinal fusion procedures; (iii) a supplemental FDA PMA database listing for the Infuse device indicating a supplemental decision approving a modification to the process for using the device, specifically the addition of an alternate water supplier; (iv) a supplemental FDA PMA database listing for the Infuse device indicating a supplemental decision approving a modification to the device, specifically the addition of alternate interbody cage designs; (v) the FDA's PMA letter for the rhBMP–2 protein approving the protein for the treatment of acute, open tibial shaft fractures stabilized with intramedullary nail fixation in skeletally mature patients; (vi) the FDA's PMA letter for the rhBMP–2 protein approving the protein for sinus augmentations and for localized alveolar ridge augmentations for defects associated with extraction sockets; (vii) an FDA "Important Medical Information" advisory regarding the Infuse device and the rhBMP–2 component thereof; and (viii) the FDA's "Summary of Safety and Effectiveness Data" for the Infuse device. *Id.* at 1-2; *Id.* at 1-2.

The general rule that a court may not consider evidence or documents beyond the complaint in the context of a Rule 12(b)(6) motion to dismiss has two exceptions. First, a court may consider documents "whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the [plaintiff's] pleading." *Knievel v. ESPN*, 393 F.3d 1068, 1076 (9th Cir. 2005) (alteration in original). Second, a court may take judicial notice of "matters of public record outside the pleadings." *Mack v. S. Bay Beer Distribs., Inc.*, 798 F.2d 1279, 1282 (9th Cir. 1986), *overruled on other grounds by Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104 (1991). While matters of public record are proper subjects of judicial notice, a court may take notice only of the authenticity and existence of a particular order or pleading, not the veracity or validity of its contents. *Lee v. City of Los Angeles*, 250 F.3d (9th Cir. 2001).

Here, neither the Bells nor Eidson have filed an opposition to Defendants' requests for judicial notice. The Court finds that because all of the documents at issue appear on the FDA's public website, they may be judicially noticed. *Paralyzed Veterans of Am. v. McPherson*, 2008 U.S. Dist. LEXIS 69542, at *5 (N.D. Cal. Sept. 8, 2008) ("Information on government agency

websites has often been treated as properly subject to judicial notice."); *United States ex rel. Dingle v. BioPort Corp.*, 270 F.Supp.2d 968, 972 (W.D. Mich. 2003) ("Public records and government documents are generally considered 'not to be subject to reasonable dispute.' This includes public records and government documents available from reliable sources on the Internet."). Further, courts have specifically held that the FDA's approval letters for medical devices are subject to judicial notice. *Rollins v. St. Jude Medical*, 538 F.Supp.2d 790, 805 (W.D. La. 2008) (a court "may take judicial notice of and consider the public records of the FDA"); *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (affirming judicial notice of FDA letter granting premarket approval to a device); *Erickson*, 846 F.Supp.2d at 1089 (taking judicial notice of FDA's supplemental approval letters for pacemaker product).

Thus, the Court grants all of Defendants' requests. The Court notes, however, that it takes judicial notice of their authenticity and existence, but not the validity of the allegations or claims made therein.

B. Regulatory Background

The Court now addresses the relevant legal framework. In 1976, Congress enacted the MDA, which "imposed a regime of detailed federal oversight" over the entry of medical devices. *Riegel*, 552 U.S. at 316. Notably, a "rigorous process" of premarket approval was established for new Class III devices. *Id.* at 316-17. To obtain PMA, a manufacturer had to submit detailed studies establishing the device's safety and effectiveness, and a description of how the device may be used. *Id.* at 318. The Supreme Court has stated:

> The FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness," § 360e(d). The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." § 360c(a)(2)(C). It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives.
>
> ...
>
> The premarket approval process includes review of the device's proposed labeling. The FDA evaluates safety and effectiveness under the conditions of use set forth on the label, §

> 360c(a)(2)(B), and must determine that the proposed labeling is neither false nor misleading, § 360e(d)(1)(A).

Id. After this review process, the FDA decides whether to grant or deny PMA to a given device. 21 U.S.C. § 360e(d).

C. Federal Preemption

1. Express Preemption

The MDA contains an express preemption provision:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court has set forth a two-step framework for determining whether the MDA expressly preempts a state law claim within the meaning of § 360k(a). First, a court must determine whether the FDA has established "requirements" applicable to the particular medical device at issue. *Riegel*, 552 U.S. at 321. If it has, the court must then determine whether the state common law claims would impose requirements that relate to safety and effectiveness and are "different from, or in addition to" the federal requirements imposed by the PMA process. *Id.* at 321-22. State "requirements" include the state's common law legal duties. *Id.* at 324-25. However, "§ 360k does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330;[2] *see also Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc) ("[T]he MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA.").

[2] In *Riegel*, the Supreme Court held that Section 360k(a) preempted state common law claims for strict products liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the device at issue. 551 U.S. at 323. The Supreme Court in *Riegel* expressly declined to consider the argument, raised for the first time on appeal, that the plaintiff's claims could be construed as "parallel" claims. *Id.* at 330.

"To properly plead parallel claims that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation." *Erickson*, 846 F.Supp.2d at 1092 (internal quotation marks omitted); *see also Simmons v. Boston Scientific Corp.*, No. CV 12-7962, 2013 WL 1207421, at *4 (C.D. Cal. Mar. 25, 2013) ("[A] plaintiff must allege that the defendant violated a particular federal specification referring to the device at issue, or identify specific PMA requirements that have been violated." (internal citations and quotation marks omitted)).

2. Implied Preemption

The MDA also states that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court interpreted § 337(a) in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), holding that it means that "the Federal Government rather than private litigants . . . are authorized to file suit for noncompliance with the medical device provisions." *Id.* at 349 n.4. In *Buckman*, "the plaintiffs asserted a state law fraud claim based on purported misrepresentations defendants made to the FDA during the PMA process for the medical device at issue. . . . The Supreme Court held that this claim was impliedly preempted because it sought to enforce an exclusively federal requirement and was not grounded in traditional state tort law." *Stengel*, 704 F.3d at 1235. The claim "existed solely by virtue" of federal requirements. *Buckman*, 531 U.S. at 353. However, courts have made clear that *Buckman* does not mean plaintiffs cannot bring state law claims based on conduct that violates the FDCA. To avoid implied preemption, a claim based on conduct that violates the FDCA must rely on traditional state tort law principles which predate the relevant FDCA requirement. As one court has noted:

> [*Buckman*] does not mean . . . that a plaintiff can never bring a state-law claim based on conduct that violates the FDCA. Indeed . . . the conduct on which the plaintiff's claim is premised must violate the FDCA if the claim is to escape express preemption by § 360k(a). Instead, to avoid being impliedly preempted under *Buckman*, a claim must rely[ ] on traditional state tort law which had predated the federal enactments in question[ ]. In other words, ***the conduct on which the claim is premised must be the type of conduct that would***

> ***traditionally give rise to liability under state law-and that would give rise to liability under state law even if the FDCA had never been enacted.*** If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA [], and the plaintiff's claim is thus impliedly preempted under *Buckman.*

Riley v. Cordis Corp., 625 F.Supp.2d 769, 776-77 (D. Minn. 2009) (internal quotations and citations omitted) (emphasis added). In sum, a claim is impliedly preempted under *Buckman* if it is cognizable only by virtue of the provisions of the FDCA itself, and would not be independently viable under state law absent those provisions. *Buckman*, 531 U.S. at 348. Conversely, a state law cause of action escapes implied preemption if it would state a claim under state law even in the absence of the FDCA. *See id.*

Considering the law regarding express and implied preemption together, it is clear that *Riegel* and *Buckman* create a narrow gap through which a plaintiff's claim can escape preemption. Notably, the plaintiff "must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley*, 625 F.Supp.2d at 777) (emphasis in original).

D. Preemption Analysis

1. First Step of *Riegel*

The Court now addresses whether each of Richard Eidson's claims are preempted under federal law. The Court does not reach whether Scott and April Bell's claims are preempted because the Court finds their claims must be dismissed without prejudice given that their factual allegations are insufficient to escape the statute of limitations bar. *See infra* Part III.E.

The first prong of the *Riegel* express preemption test is whether the FDA has established "requirements" for the subject device. That prong is clearly met in this case. In *Riegel*, where the court held that § 360k(a) expressly preempted common law claims challenging a Class III catheter that had received PMA, the court determined that PMA "imposes 'requirements' under the MDA" because "[u]nlike general labeling duties . . . [PMA] is specific to individual devices." 552 U.S. at

322-23. The same is true here; the Infuse Device was approved by the FDA, and such PMA imposes federal "requirements" that are specific to the device. *Id.* at 322-23.[3] Thus, the first prong of the *Riegel* express preemption test is met.

2. Second Step of *Riegel*

The Court proceeds to ask whether Eidson's state law claims are based on "any requirement" of California law that is "different from, or additional to" federal requirements applicable to the Infuse Device, and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." § 360k(a). The Supreme Court has held that "reference to a State's 'requirements' includes its common-law duties." *Riegel*, 552 U.S. at 324. Thus, the state tort law duties under which Eidson sues are considered "requirements." Safety and effectiveness are also the key concerns of Eidson's claims, so the central question is whether California laws impose duties "different from, or additional to" the federal requirements. Below, the Court addresses this question for each of Eidson's four tort claims: 1) fraudulent misrepresentation and fraudulent inducement; 2) strict products liability

[3] Eidson objects, arguing that the first step of *Riegel* is not met because the particular "medical device" at issue is only the Infuse Bone Graft that was used in his surgery (without the LT Cage). Eidson MTD Opp. at 10-12. Eidson claims that the PMA process for the Infuse Device only established federal requirements for the Infuse Bone Graft used *in conjunction* with the LT Cage, but not the Infuse Bone Graft used alone. *Id.* Thus, Eidson claims that no federal requirements apply to the particular medical device (the Infuse Bone Graft) that is the object of his lawsuit. *Id.* Several courts have rejected Eidson's argument, and this Court does as well. In *Bass v. Stryker Corp.*, 669 F.3d 501 (5th Cir. 2012), the Fifth Circuit held that the district court did not err in finding that PMA granted for a medical device also established specific federal requirements applicable to a component of the medical device at issue. Persuasive authority from other courts in almost identical Infuse Device cases also suggests that the preemption analysis should not be applied differently to the component parts of a medical device and the medical device that received PMA. *Houston v. Medtronic, Inc.*, No. 2:13–cv–1679–SVW–SH., 2013 WL 3927839 (C.D. Cal. July 30, 2013); *Gavin v. Medtronic, Inc.*, 2013 WL 3791612 (E.D. La. July 19, 2013); *see also Riley*, 625 F.Supp.2d at 779-80 (holding that "components of a PMA-approved device work together as a single medical device" and thus "it makes no sense . . . to pick apart the components of a medical device and apply different preemption analyses to different components"); *Duggan v. Medtronic, Inc.*, 840 F.Supp.2d 466, 471 (D. Mass. 2012) ("Once premarket approval is granted, all claims relating to all components of the device are preempted").

(misrepresentation); 3) strict products liability (failure to warn); and 4) products liability (negligence).

a. Fraud-Based Claims: Fraudulent misrepresentation, fraudulent inducement, and strict products liability (misrepresentation)

Eidson's fraudulent misrepresentation and fraudulent inducement claims are one and the same, as categorized in his complaint. Eidson Complaint at 62. However, Eidson does not clearly articulate the theory underlying this claim. With respect to this claim, Eidson alleges "Defendants fraudulently and intentionally misrepresented material and important health and safety product risk information from Plaintiff and Plaintiff's physicians." Eidson Complaint ¶ 284. Specifically, Eidson also alleges: 1) "Defendants fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label use of Infuse®;" 2) "Defendants fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physician, the practice of using Infuse® off-label by utilizing a posterior-approach, using Infuse® for an off-label indication, and by using Infuse® without an LT Cage;" 3) "Defendants fraudulently concealed and misrepresented information about the known comparative risks and benefits of the use of Infuse® and the relative benefits and availability of alternate products, treatments and/or therapies;" and 4) "Plaintiffs' physicians were justified in relying, and did rely, on Defendants' concealment of information and misrepresentations about the safety risks related to Infuse® in deciding to make off-label use of Infuse for lumbar spine fusion surgery. As the direct, proximate and legal cause and result of the Defendants' fraudulent concealment and misrepresentations . . . , Plaintiff has been injured." *Id.* ¶ 287-289, 293.

Although it is not clear to the Court what theory underlies Eidson's fraudulent misrepresentation/fraudulent inducement claim, the Court surmises two possible theories: 1) the claim is based on alleged misrepresentations and omissions contained in the actual warnings and labels accompanying the Infuse Device; and/or 2) the claim is based on alleged misrepresentations and omissions Defendants made while promoting the off-label use of the Infuse Device. As

discussed below, the Court finds that to the extent the claim is based on the first theory, it is expressly preempted. To the extent it is based on the second theory, the Court finds it is not expressly or impliedly preempted.

With respect to Eidson's strict products liability misrepresentation claim, Eidson alleges that Defendants made untrue representations of materials facts and omitted material information to the public. Specifically, Eidson states:

> "In the course of marketing Infuse®, the MEDTRONIC Defendants made untrue representations of material facts and omitted material information to Plaintiff, Plaintiff's physicians, and the public at large. The MEDTRONIC Defendants sponsored biased medical trials, reports, and articles that wrongfully and inaccurately claimed that the dangers inherent to off-label use of Infuse® did not exist or were significantly less than the actual dangers."

Id. ¶ 322. Based on these allegations, the Court surmises only one possible theory underlying Eidson's strict products liability misrepresentation claim. The Court finds that the claim is based on alleged misrepresentations and omissions Defendants made while promoting the off-label use of the Infuse Device. As discussed below, the Court finds that this claim is not expressly or impliedly preempted.

The Court will now address each of the two theories underlying Eidson's fraudulent misrepresentation/fraudulent inducement claim, and then the theory underlying Eidson's strict products liability misrepresentation claim.

i. First Theory

To the extent that Eidson's fraudulent misrepresentation/fraudulent inducement claim is based upon alleged misrepresentations and omissions contained in the actual warnings and labels accompanying the Infuse Device, the Court finds persuasive the reasoning in *Caplinger v. Medtronic*, 921 F.Supp.2d 1206, 1219 (W.D. Okl. Feb. 6, 2013), a case involving the Infuse Device. In *Caplinger*, the court held that the plaintiff's fraudulent misrepresentation/fraudulent inducement claim based upon alleged misrepresentations and omissions contained in the actual warnings and labels accompanying the Infuse Device was expressly preempted because "allowing [such a] claim to proceed would permit a finding that Defendants were required to alter the Infuse

Device's warning and label and to provide additional warnings above and beyond those on the Infuse Device's label and accompanying the device — a label and warnings that were specifically approved by the FDA as part of the PMA process." Similarly, in the instant case, requiring Defendants to alter the Infuse Device's warnings and label in order to provide extra warnings beyond those already approved during the PMA process would impose labeling and warning requirements "different from, or in addition to" federal requirements for the Infuse Device. As the Supreme Court stated in *Riegel*, state tort claims are expressly preempted if they impose requirements that are "different from, or in addition to" the federal requirements imposed by the PMA process. 552 U.S. at 321-22. Thus, the Court finds that to the extent Eidson's fraudulent misrepresentation/fraudulent inducement claim is based upon alleged misrepresentations and omissions contained in the actual warnings and labels accompanying the Infuse Device, the claim is expressly preempted.

ii. Second Theory

Eidson's fraudulent misrepresentation/fraudulent inducement claim may also be based upon alleged misrepresentations and omissions Defendants made while promoting the off-label use of the Infuse Device. Similarly, Eidson brings his strict products liability misrepresentation claim on the theory that while promoting off-label uses, Defendants fraudulently omitted or misrepresented material facts to Eidson and his physician. The Court finds that Eidson's fraudulent misrepresentation/fraudulent inducement claim based on this second theory and Eidson's strict products liability misrepresentation claim are not expressly preempted because these state law claims impose duties that parallel federal requirements, as explained below.

Federal regulations prohibit device manufacturers from promoting or advertising off-label uses of medical devices because such advertising is deemed to be false or misleading.[4] *See, e.g.*,

[4] The Infuse Device is a "restricted device." 21 U.S.C. §§ 360e(d)(1)(B)(ii), 360j (e). A restricted device is "misbranded" and thus prohibited, if its advertising is false or misleading. 21 U.S.C. §§ 331(a), 352(q)(1). "An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, among other reasons, if it: (I) contains a representation or suggestion, *not approved or permitted for use in the labeling*, that a drug is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience." 21 C.F.R. § 202.1(e)(6) (emphasis added).

Carson v. Depuy Spine, Inc., 365 Fed. App'x 812, 815 (9th Cir. 2010) ("[W]hile doctors may use a drug or device off-label, the marketing and promotion of a Class III device for an unapproved use violates Section 331 of the FDCA."); *In re Epogen & Aranesp Off-Label Marketing & Sales Practices Litigation*, 590 F.Supp.2d 1282, 1287 (C.D. Cal. 2008) ("Under FDA regulations, drug manufacturers are prohibited from promoting off-label uses of prescription drugs."). In *Houston*, a highly analogous case involving the Infuse Device, the court held that the plaintiff's fraudulent misrepresentation/fraudulent inducement claim and strict products liability misrepresentation claim based on the defendants' off-label promotion of the Infuse Device were not expressly preempted. *Houston*, 2013 WL 3927839, at *10. The *Houston* court reasoned that because federal law forbids manufacturers from promoting off-label uses, the plaintiff's claims were parallel to federal law because there was "no likelihood that Defendants could be held liable under state law without having violated the federal law." *Id.*, at *10; *see also In Re Epogen*, 590 F.Supp.2d at 1291 (holding that state consumer fraud claims based on defendant's alleged fraudulent statements made to promote off-label uses were not preempted by the FDCA).[5] The Court finds the reasoning of the *Houston* court persuasive. Here, as in *Houston*, the state tort law duties underlying Eidson's three claims are not "different from, or in addition to" the federal requirement banning off-label promotion. Rather, the state law claims are premised on a violation of the federal law banning off-label promotion. Accordingly, the duties imposed by Eidson's three fraud claims lie parallel to federal requirements, and thus the Court finds that Eidson's three fraud claims are not expressly preempted.

The Court also finds that Eidson's fraudulent misrepresentation/fraudulent inducement and strict products liability misrepresentation claims based on off-label promotion are not impliedly preempted because these claims are based on state common law tort duties that exist independently

[5] Defendants rely on a Second Circuit case to claim that off-label promotion is not actually a violation of federal law. Eidson MTD at 12 (citing *United States v. Caronia*, 703 F.3d 149, 160 (2d. Cir. 2012) which states, "While the FDCA makes it a crime to misbrand or conspire to misbrand a drug, the statute and its accompanying regulations do not expressly prohibit or criminalize off-label promotion."). However, Defendants' partial citation is misleading, as the Second Circuit ultimately held that the FDA has "construed the FDCA to prohibit promotional speech as misbranding itself." *Caronia*, 703 F.3d at 154-55.

from the FDCA and not solely by virtue of the FDCA. Under *Buckman*, so long as a state law claim exists independently of federal requirements and does not exist "solely by virtue" of those federal requirements, there is no implied preemption. *Buckman*, 521 U.S. at 353. District courts in the Ninth Circuit have come to the same conclusion in almost identical cases involving the Infuse Device. *See Houston*, 2013 WL 3927839, at *10 ("Plaintiff's fraudulent advertising claims are not impliedly preempted under *Buckman* because they are moored in traditional state common law that exists independently from the FDCA"); *Alton v. Medtronic*, No. 3:13-CV-409-PK, 2013 WL 4786381, at *23-24, 29 (D.C. Or. Sept. 6, 2013) (holding that plaintiff's fraud claims and strict liability misrepresentation claim premised on Medtronic's alleged misrepresentations while promoting off-label uses of the Infuse Device were not impliedly preempted because they stated claims under state law that existed independently of the FDCA); *Ramirez v. Medtronic Inc.*, CV-13-00512-PHX-GMS, 2013 WL 4446913, at *14-*16 (D. Ariz. Aug. 21, 2013) (same).

iii. FRCP 9(b) for Fraud Claims

Defendants also argue Eidson's fraud claims, that is Eidson's fraudulent misrepresentation/ fraudulent inducement and strict products liability misrepresentation claims, should be dismissed on the alternative ground that the claims are not pled with the requisite particularity required under Federal Rule of Civil Procedure 9(b). Defendants argue that "[n]owhere ha[ve] Plaintiffs pled the specific circumstances surrounding any alleged misrepresentations or omissions made by Medtronic." Eidson MTD at 16-17. Federal Rule of Civil Procedure 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b).

The Court holds that Eidson's allegations are pled with adequate particularity. The details of his allegations that Medtronic fraudulently concealed and misrepresented the health risks associated with off-label applications of Infuse, and specifically with PLIF surgery using only the Infuse Bone Graft, are pled with voluminous particularity. The complaint alleges Medtronic orchestrated a marketing campaign in which false and misleading statements and publications were made by Medtronic's paid "Opinion Leaders" and its own sales representatives. *Id.* ¶¶ 11, 172-

221; *Id.* ¶¶ 10, 171-220. The complaint also identifies many of the "Opinion Leaders" by name, describes their role in promoting off-label uses of Infuse and concealing the safety risks, and summarizes the financial gifts they received from Medtronic in exchange. *Id.*

Because Medtronic is on sufficient notice of the particular misconduct alleged to have constituted fraud to permit Medtronic to litigate its defense, Medtronic's motion to dismiss is denied to the extent the motion is based on lack of particularity in the pleading of Eidson's fraud claims. *See Alton*, 2013 WL 4786381, at * 31 (holding, in analogous case regarding preemption of state tort law claims regarding Infuse Device, that fraud claims satisfied Rule 9(b)).

iv. Conclusion

In sum, the Court finds that Eidson's fraudulent misrepresentation/fraudulent inducement claim is expressly preempted to the extent it is based on alleged misrepresentations and omissions contained in the actual warnings and labels accompanying the Infuse Device. However, to the extent the claim is based upon alleged misrepresentations and omissions Defendants made while promoting off-label uses, the claim is not preempted. Eidson's strict products liability misrepresentation claim is also not preempted. Defendants' motion to dismiss these three fraud claims is thus DENIED.

b. Strict products liability — failure to warn

In his complaint, Eidson alleges: 1) "The warnings accompanying the Infuse® product did not adequately warn Plaintiff and his physicians, in light of its scientific and medical knowledge at the time, of the dangers associated with Infuse® when used off-label by utilizing a posterior approach, using Infuse® for an off-label indication, and by using Infuse® without an LT Cage and in a manner not otherwise approved by the FDA, including, but not limited to, pain and weakness in limbs, loss of sensation, radiculitis, subsidence, ectopic bone formation, osteolysis, and poorer global outcomes than alternative treatments;" and 2) "The warnings accompanying the Infuse® product failed to provide the level of information that an ordinary physician or consumer would expect when using the product in a manner reasonably foreseeable to Medtronic. Medtronic either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to

the off-label use of Infuse®, including, but not limited to, pain and weakness in limbs, loss of sensation, radiculitis, subsidence, ectopic bone formation, osteolysis, and poorer global outcomes than alternative treatments." Eidson Complaint ¶ 301-302.

Based on the above allegations, it is not clear to the Court what theory underlies Eidson's strict products liability failure to warn claim. However, the Court surmises two possible theories: 1) the claim is based on Defendants' failure to include warnings beyond those in the FDA-approved label or failure to issue appropriate warnings regarding the dangers of off-label use; and/or 2) the claim is based on Defendants' failure to report to the FDA adverse events regarding the dangers of off-label use. As discussed below, the Court finds that to the extent the claim is based on the first theory, the claim is expressly preempted. To the extent the claim is based on the second theory, the Court finds it is not expressly or impliedly preempted but nonetheless must be dismissed for failure to establish a causal nexus between Eidson's alleged injury and the alleged legal violation by Defendants.

The Court will now address each of the two theories underlying Eidson's claim.

i. First Theory

First, to the extent the claim is based on Defendants' failure to include warnings beyond those in the FDA-approved label or failure to issue appropriate warnings regarding the dangers of off-label use, the Court finds the claim is expressly preempted and should be dismissed with prejudice. As the Supreme Court stated in *Riegel*, 552 U.S. at 321-22, state tort claims are expressly preempted if they impose requirements that are "different from, or in addition to" federal requirements. A failure to warn claim that imposes obligations on Defendants beyond those imposed during the PMA process does just that; it imposes warning requirements "in addition to" federal requirements. Other courts in the Ninth Circuit have reached this conclusion. *See Houston*, 2013 WL 3927839, at *7-*8 (finding strict products liability failure to warn claim expressly preempted because "a jury would have to find either that Defendants were required to include warnings beyond those in the FDA-approved label for the Infuse Device or that Defendants were obligated to issue post-sale warnings about potential adverse effects of using the Infuse Device in

an off-label manner," while FDA regulations do not require such post-sale warnings); *see also Dawson v. Medtronic*, No. 3:13–cv–663–JFA, 2013 WL 4048850, at *7 (D.S.C. Aug. 9, 2013) (finding, in case involving the Infuse Device, that failure to warn claim was expressly preempted because it would require defendants to adhere to warning and labeling requirements "different from or in addition to the federal requirement set through the PMA process"); *Caplinger*, 921 F.Supp.2d at 1221 ("Allowing plaintiff's strict products liability failure to warn claim to proceed would permit a finding that defendants were required to provide warnings above and beyond those on the Infuse Device's label and accompanying the device—a label and warnings that were specifically approved by the FDA as part of the PMA process.")

ii. Second Theory

Eidson argues that his failure to warn claim is a parallel claim that is not expressly preempted because it is based on Defendants' failure to report to the FDA adverse events regarding the dangers of off-label use, as required by federal law. Eidson MTD Opp. at 15-18 (arguing the state tort claim duties lie parallel to "the FDCA requirement that medical devices manufacturers report adverse events to the FDA."); *see also* 21 C.F.R. § 803.50(a) (FDA regulation requiring manufacturers to report any information "reasonably suggest[ing]" that one of their devices "[m]ay have caused or contributed to a death or serious injury"). The Court agrees with Eidson, as his theory is highly analogous to the one alleged in *Stengel*, where the Ninth Circuit held that the plaintiffs' negligence claim for failure to report adverse events to the FDA regarding Defendants' device was not expressly preempted because the "state-law duty parallel[ed] [the] federal-law duty" to report adverse events to the FDA. *See Stengel*, 704 F.3d at 1223. *Stengel* also held there was no implied preemption, as the "state-law claim [was] independent of the FDA's pre-market approval process that was at issue in *Buckman*." *Id.* at 1233. The *Stengel* concurring opinion provided further reasoning for this holding, noting that the plaintiff's claim relied on traditional state tort law which predated the federal regulation at issue, and thus did not "exist[] solely by virtue of the federal enactments." *Stengel*, 704 F.3d at 1235 (Watford, J., concurring) (citing *Buckman*, 531 U.S. at 353). This was because "Medtronic's failure to report was more than a mere

misrepresentation to the FDA because it simultaneously misled the device's current and potential users, to whom Medtronic owed an independent duty under state law." *Id.*

Courts addressing almost identical cases as the instant case have followed *Stengel* and found no preemption of claims identical to Eidson's claim, and this Court agrees.[6] *See Ramirez*, 2013 WL 4446913, at *20-21 (following *Stengel* and declining to dismiss a "failure to warn" claim under state law premised on defendants' failure to report adverse events to the FDA regarding the Infuse Device); *Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *14 (same). Nonetheless, as discussed further below, although Eidson's claim is not expressly or impliedly preempted, his allegations, as they currently stand, are insufficient due to Eidson's failure to establish a causal nexus between his alleged injuries and the Defendants' alleged failure to report adverse events to the FDA.

Although Eidson does not articulate the theory underlying his "failure to warn" claim in the "failure to warn" claim section in his complaint, Eidson does allege in the "factual background" section of his complaint that Medtronic failed to report certain adverse events to the FDA. Eidson Complaint ¶¶ 105, 128-131, 164, 277. These allegations state in relevant part:

> "Confidential Witness 15 discussed the complaints related to Infuse® at meeting with [Medtronic high-ranking officers] to decide whether or not certain adverse events should be reported to the FDA." *Id.* ¶ 105.
>
> "Medtronic . . . fail[ed] to account for adverse events and update its labeling, directions for use, and advertising to account for adverse events resulting from these off-label uses." *Id.* ¶ 129.

[6] Defendants provide no persuasive reason why *Stengel* is distinguishable. Instead, they cite *Pinsonneault v. St. Jude Medical*, Nos. 12–1717, 12–1785, 12–2396, 2013 WL 3717780 (D. Minn. June 18, 2013), but this citation is unavailing. Eidson MTD Reply at 9. In *Pinsonneault*, the court found express and implied preemption of the plaintiffs' failure to warn claim, which was based on the alleged failure by the defendants to report adverse events to the FDA regarding their devices. The court distinguished *Stengel*, noting that unlike in *Stengel*, the *Pinsonneault* plaintiffs conceded that the duty to report arose only under federal law, and thus the failure to report was "not the type of conduct that would traditionally give rise to liability under state law even if the FDCA had never been enacted." *Id.* at *9. Here, Eidson, like the plaintiff in *Stengel*, does not claim that the duty to report is grounded only in federal law, and in fact cites a specific California tort law duty on manufacturers to warn others of the potential dangers of their products. *See Carlin v. Superior Court*, 13 Cal.4th 1104, 1110-12 (1996).

> "Medtronic's violation of the FDCA statutes and accompanying regulations, as discussed above, directly caused or significantly contributed to the off-label use of Infuse® generally, and directly caused or significantly contributed to the off-label use of Infuse® in this particular Plaintiff, and Medtronic's misconduct in this regard thus caused or contributed to Plaintiff's injuries and damages." *Id.* ¶ 131.

> "Medtronic's off-label promotion activities and failure to report adverse events caused spine surgeons, including Plaintiff's surgeon to use Infuse in dangerous off-label procedures." *Id.* ¶ 277.

> "Medtronic failed to report the death of this patient [who had undergone an off-label operation] until three months after it occurred. . . . While the company filed an adverse event report with the FDA immediately following the procedure, Medtronic did not inform the agency of her death until after a lawsuit was filed by the patient's family and reported in the Wall Street Journal." *Id.* ¶ 164.

The problem with these allegations is that although Eidson generally asserts that the Defendants' failure to report to the FDA "caused" his injuries, he does not state with any specificity *how* it caused them. *See Erickson v. Boston Scientific Corp.*, 846 F.Supp.2d 1085, 1092 (C.D. Cal. 2011) ("To properly plead parallel claims that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation.") For example, he does not allege how the one reporting violation which he actually identifies (*see* Eidson Complaint ¶ 164: failure to timely report the death of a patient who had an off-label surgery) had a causal effect on his injuries. *C.f. Simmons*, 2013 WL 1207421, at *5 ("a failure to notify the FDA of Diana Simmons' injury could have no causal relationship to the injury she suffered.") Specifically, Eidson's complaint does not specify the date on which the patient died or the date on which Defendants reported the patient's death to the FDA. Eidson Complaint ¶ 164. Thus, the Court has no basis to evaluate whether the failure to report may have had a causal effect on Eidson's injuries. Even assuming the patient's death occurred before Eidson's surgery, thus suggesting that Defendants' act of reporting the death to the FDA may have prevented Eidson's surgeon from utilizing Infuse in an off-label way in Eidson's surgery, Eidson has failed to make that causal allegation in his complaint. Thus, Eidson's complaint as it stands insufficiently pleads a failure to warn claim based on Defendants' alleged failure to report adverse events to the FDA.

iii. Conclusion

The Court finds that Eidson's strict products liability failure to warn claim is preempted to the extent that it is based on Defendants' failure to include warnings beyond those in the FDA-approved label or failure to issue appropriate warnings regarding the dangers of off-label use. However, to the extent Eidson's claim is based on Defendants' failure to report adverse events to the FDA, the claim is not preempted, but should nonetheless be dismissed without prejudice for failure to establish a causal nexus between the alleged injury and the alleged violation. The Court thus GRANTS Defendants' motion to dismiss this claim but grants leave to amend so that Eidson may cure the defects in his complaint.

c. Products liability — Negligence

The allegations in Eidson's complaint with respect to his negligence claim do not clearly identify what theory underlies this claim. Eidson generally alleges that Defendants had a duty to warn him of the health risks related to the off-label use of Infuse. He alleges:

> "[Defendants] had an affirmative duty to fully and adequately warn Plaintiff and Plaintiff's physicians of the true health and safety risks related to the off-label use of Infuse®, and Defendants had a duty to disclose their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® by utilizing a posterior approach, using Infuse® for an off-label indication, and by using Infuse® without an LT Cage and in a manner otherwise not approved by the FDA. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of the off-label use of Infuse® to Plaintiff and Plaintiff's physicians."

Eidson Complaint ¶ 333.

Eidson also specifically alleges "[m]isrepresentations made by Defendants about the health and safety of Infuse® independently imposed a duty upon Defendants to fully and accurately disclose to Plaintiff and Plaintiff's physicians the true health and safety risks related to Infuse®, and a duty to disclose their dangerous and irresponsible off-label promotion and marketing practices." *Id.* ¶ 334. Eidson further alleges the following to establish defendants' liability for negligence: 1) "Defendants negligently promoted and marketed Infuse® to physicians, including for off-label use in lumbar spine fusion surgeries;" 2) "Defendants negligently failed to warn physicians and Plaintiff of the dangers associated with Infuse® when used off-label by utilizing a

posterior approach, using Infuse® for an off-label indication, and by using Infuse® without an LT Cage and in a manner otherwise not approved by the FDA, including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes than alternative treatments;" and 3) "Defendants negligently failed to exercise reasonable care in that they failed to comply with federal law and regulations applicable to the sale and marketing of Infuse®." *Id.* ¶ 336.

Although it is not clear to the Court what theory underlies Eidson's neligence claim, the Court surmises three possible theories: 1) the claim is based upon Defendants' failure to report adverse events to the FDA; 2) the claim is based upon Defendants' promotion of the Infuse Device for off-label uses; and/or 3) the claim is based upon some other violation of federal law. As discussed below, the Court finds that to the extent the claim is based on the first theory, it is not expressly or impliedly preempted, but should nonetheless be dismissed without prejudice for failure to establish a causal nexus between the alleged injury and the alleged violation. To the extent the claim is based on the second theory, the Court finds it is impliedly preempted. To the extent the claim is based on the third theory, it is expressly preempted.

The Court will now address each of the three theories underlying Eidson's claim.

i. First Negligence Theory

To the extent the claim is based upon Defendants' failure to include warnings beyond those in the FDA-approved label or failure to issue appropriate warnings regarding the dangers of off-label use, the Court finds the claim should be dismissed with prejudice, as it is expressly preempted for precisely the same reason that the first possible basis for Eidson's strict liability failure to warn claim was preempted. Namely, allowing such a claim would permit a finding that Defendants were required to provide warnings other than those the FDA has already approved. As the Supreme Court stated in *Riegel*, 552 U.S. at 321-22, state tort claims are expressly preempted if they impose requirements that are "different from, or in addition to" federal requirements. A negligence claim that imposes obligations on Defendants beyond those imposed during the PMA process does just that; it imposes warning requirements "in addition to" federal requirements. Other courts in the

Ninth Circuit have come to the same conclusion with respect to highly analogous claims. *See Houston*, 2013 WL 3927839, at *9 (finding negligence claim premised on failure to warn theory in Infuse Device case expressly preempted because it "proceed[ed] on the theory that state law required Defendants to issue warnings about the risks of off-label uses, or make cost-benefit decisions about the device design, 'different from' or 'in addition to' what applicable federal requirements demand.") (citation omitted); *see also Dawson*, 2013 WL 4048850, at *7 (holding that negligence claim based on failure to warn in Infuse Device case was expressly preempted); *Caplinger*, 921 F.Supp.2d at 1223 (same).

However, as with his strict products liability failure to warn claim, Eidson asserts that his failure to warn claim grounded in negligence law is based on Defendants' failure to report adverse events to the FDA, and thus not preempted under *Stengel*. Eidson MTD Opp. at 15,18. For the same reasons discussed above, *see supra* Part III.D.2.b, the Court agrees. The Ninth Circuit held in *Stengel* that a negligence claim for failure to report adverse events to the FDA was not expressly or impliedly preempted. However, due to Eidson's failure to establish a causal nexus between his alleged injury and Defendants' alleged legal violation, *see supra* Part III.D.2.b, the Court GRANTS Defendants' motion to dismiss the claim with leave to amend to the extent the claim is based on this theory.

ii. Second Negligence Theory

To the extent Eidson's negligence claim is based on Defendants' promotion of the Infuse Device for off-label uses, such a claim imposes duties that are parallel to duties under federal law and thus not expressly preempted, for the same reason his fraud claims based on off-label promotion are not preempted. *See supra* Part III.D.2.a. However, the Court finds that Eidson's negligence claim based on Defendants' promotion of off-label use is impliedly preempted. Under *Buckman*, so long as a state law claim exists independently of federal requirements and does not exist "solely by virtue" of those federal requirements, there is no implied preemption. *Buckman*, 521 U.S. at 353. Here, Eidson's negligence claim based on off-label promotion is not based on any conduct that would give rise to a recovery under state law even in the absence of the FDCA.

Defendants' conduct is only allegedly "negligent" because the FDCA bans off-label promotion. Thus, although styled as a negligence claim, the claim is in substance a claim for violating the FDCA and exists solely by virtue of the federal ban on off-label promotion. The state law claim does not exist independently of federal requirements. District courts in the Ninth Circuit have adopted this reasoning and come to this conclusion in almost identical cases involving the Infuse Device. *See Houston*, 2013 WL 3927839, at *8-*9 (holding that "any negligence claim based solely on illegal off-label promotion is impliedly preempted under *Buckman*" because "[l]ike the 'fraud on the FDA' claim in *Buckman*, the instant claim that Defendants engaged in illegal off-label marketing of the Infuse Device 'exist[s] solely by virtue' of federal regulations, and is not rooted in any traditional state tort law."); *c.f. Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1119-20 (9th Cir. 2013) (holding that fraud-by-omission claim was impliedly preempted because it was premised on defendant's failure to disclose that the off-label use of the device at issue had not been approved by the FDA, and thus the claim existed "solely by virtue of the FDCA . . . requirements").

iii. Third Negligence Theory

To the extent Eidson's claim is based on some other violation of federal law, he has not alleged sufficient facts to establish a claim imposing parallel duties, and thus the claim is expressly preempted. He alleges that "Defendants negligently failed to exercise reasonable care in that they failed to comply with *federal law and regulations* applicable to the sale and marketing of Infuse®." Eidson Complaint ¶ 336 (emphasis added). However, Eidson "cannot simply incant the magic words '[Defendant] violated FDA regulations' in order to avoid preemption." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011). This Court finds persuasive the reasoning of courts that have held that merely alleging that Defendants failed to exercise reasonable care "by not complying with federal law and regulations applicable to the sale and marketing" of the Infuse Device is insufficient to overcome express preemption without some factual detail as to how Defendants violated the federal regulations. *See Caplinger*, 921 F.Supp.2d, at *16 (holding that the vague allegation that defendants violated federal law is "insufficient to overcome" preemption);

Houston, 2013 WL 3927839, at *9 (finding negligence claim based on "some other violation of federal law" expressly preempted because the "plaintiff must allege facts to substantiate that Defendants violated a particular federal requirement applicable to the subject device").

iv. Conclusion

The Court finds Eidson's negligence claim must be dismissed to the extent it relies upon the second and third theories described above. However, to the extent it is grounded upon Defendants' failure to report adverse events to the FDA, the claim is not preempted but is nonetheless dismissed without prejudice due to Eidson's insufficient allegations regarding the causal nexus between Eidson's alleged injury and Defendants' failure to report adverse events to the FDA. Eidson is granted leave to amend to cure the defects in his complaint, as discussed above. *See supra* Part III.D.2.b. The Court thus GRANTS Defendants' motion to dismiss Eidson's negligence claim without prejudice.

d. Strict Products Liability – Design defect claim

As Defendants argue, California law precludes liability for manufacturers of prescription medical devices under a design defect theory. Edison MTD at 16; *see Garrett v. Howmedica Osteonics Corp.*, 214 Cal. App. 4th 173, 182 (2013) (holding that "a manufacturer of prescription drugs cannot be strictly liable for a design defect" and "that the appropriate test for determining a prescription drug manufacturer's liability for a design defect involves an application of the ordinary negligence standard"). Eidson concedes that California law bars his strict liability claim for design defect. Eidson MTD Opp. at 2. Thus, the Court GRANTS Defendants' motion to dismiss this claim with prejudice on this basis and does not reach whether the claim would be preempted under *Buckman* or *Riegel*.

E. Statute of Limitations Bar against Scott and April Bell's cause of action

Defendants argue that Scott and April Bell's claims are barred by the statute of limitations, and should be dismissed on this alternative ground. Bell MTD at 15-20. The Bells do not address this argument in their opposition brief. *See generally* Bell MTD Opp. For the following reasons,

the Court finds that the Bells have failed to allege facts to circumvent the statute of limitations bar, and thus DISMISSES all of their claims with leave to amend.

In a federal diversity action brought under state law, the state statute of limitations governs. *Bancorp Leasing & Fin. Corp. v. Agusta Aviation Corp.*, 813 F.2d 272, 274 (9th Cir. 1987). California Civil Procedure Code § 335.1 sets a two-year statute of limitations on personal injury claims based upon defective products, regardless of the particular legal theory invoked. *Soliman v. Philip Morris Inc.*, 311 F.3d 966, 971 (9th Cir. 2002). Thus, all of the Bells' claims are subject to a two-year statute of limitations. The Code of Civil Procedure also states that a plaintiff must bring a claim within the limitations period after accrual of the cause of action. Code Civ. Proc. § 312 ["Civil actions, without exception, can only be commenced within the periods prescribed in this title, after the cause of action shall have accrued"]. The general rule for defining the accrual sets the date "as the time when, under the substantive law, the wrongful act is done, or the wrongful result occurs, and the consequent liability arises." *Norgart v. Upjohn Co.*, 21 Cal. 4th 383, 397 (1999). An important exception is the "discovery rule," which postpones accrual until the plaintiff discovers, or has reason to discover, the cause of action. *Id.*

In order to rely on the discovery rule for delayed accrual of a cause of action, "[a] plaintiff whose complaint shows on its face that his claim would be barred without the benefit of the discovery rule must specifically plead facts to show (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 920 (2005) (citation omitted). In assessing the sufficiency of the allegations of delayed discovery, the plaintiff has the burden to "show diligence"; "conclusory allegations will not withstand demurrer." *Id.* at 921. "Formal averments or general conclusions to the effect that the facts were not discovered until a stated date, and that plaintiff could not reasonably have made an earlier discovery, are useless." *Anderson v. Brouwer*, 99 Cal. App. 2d 176, 182 (1979). Further, "the statute of limitations begins to run when the plaintiff suspects or should suspect that her injury was caused by wrongdoing . . ." *Jolly v. Eli Lilly & Co.*, 44 Cal.3d

1103, 1110 (1988) (holding that "the limitations period begins once the plaintiff has notice or information of circumstances to put a reasonable person on inquiry").

In this case, Scott Bell was implanted with the Infuse Device in 2005. Bell Complaint ¶ 279. Later, in March 2007, he was "diagnosed with advanced bony overgrowth," which is the injury over which he is suing. *Id.* ¶ 281. He underwent corrective surgery in May 2007, when his surgeon "discovered large columns of bone emanating from the disc space." *Id.* Given that the Bells filed this lawsuit in April 2013, some six years after Scott Bell's injury occurred, their complaint is barred by the two year statute of limitations unless they sufficiently plead facts showing they deserve the benefit of the discovery rule.

The Bells fail to meet their burden. All that the Bells offer in their complaint is:

> Despite diligent investigation by Plaintiff into the cause of his injuries, including numerous consultations with Mr. Bell's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to INFUSE was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentation and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with INFUSE. As a result of Defendants' fraudulent concealment, Plaintiff was unaware, and could not have known or have learned through reasonable diligence, that Plaintiff have [sic] been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

Bell Complaint ¶ 283.

The Bells fail specifically to plead facts under both prongs of the *Fox* test. First, they fail to plead facts alleging the time and manner of their discovery that the Infuse Device had allegedly caused Scott Bell's injuries. They merely state they did not discover "the nature of Plaintiff's injuries, and their relationship to Infuse" until a certain date within the statute of limitations period. This does not describe the manner of their discovery, nor does it provide a certain time at which they discovered the connection between Infuse and the injuries. Regarding prong two, the Bells' allegation that they undertook "diligent investigation . . . into the cause of his injuries" is merely conclusory; the Bells do not offer any facts establishing what steps they actually took to investigate after they discovered Scott Bell's bony overgrowth or after he underwent the "corrective surgery"

in May 2007. They also do not offer any facts demonstrating why despite their alleged "diligence," they were unable to discover the connection "until a date within the applicable statute of limitations," other than to blame Defendants for making misrepresentations and omissions. They do not explain how Defendants' alleged actions delayed their discovery. "Formal averments or general conclusions to the effect that the facts were not discovered until a stated date, and that plaintiff could not reasonably have made an earlier discovery, are useless." *Anderson v. Brouwer*, 99 Cal. App. 2d 176, 182 (1979).[7]

Accordingly, the Court finds that the Bells' complaint does not allege enough facts to satisfy the pleading requirements of the discovery rule and therefore must be dismissed on statute of limitations grounds. However, under Rule 15, leave to amend "should be freely granted when justice so requires." *Lopez*, 203 F.3d at 1127. Thus, the Bells' claims are DISMISSED without prejudice with leave to amend to allege additional facts regarding discovery.

IV. CONCLUSION

The Court DENIES Defendants' motion to dismiss Eidson's three fraud claims. The Court GRANTS with leave to amend Defendants' motion to dismiss Eidson's negligence and strict products liability failure to warn claims. The Court GRANTS Defendants' motion to dismiss Eidson's strict products liability design defect claim with prejudice. The Court GRANTS Defendants' motion to dismiss all of Scott and April Bell's claims with leave to amend. Plaintiffs must amend their complaints within thirty days of the filing date of this order. Failure to cure the deficiencies identified in this order will result in dismissal of the complaints with prejudice. The

[7] Indeed, without further factual allegations, the Court finds persuasive Defendants' argument that Plaintiffs should have suspected that the Infuse Device was allegedly defective well before the lawsuit was filed in April 2013, and thus that the statute of limitations period of two years has expired, thus barring Plaintiffs' claims. This is because Plaintiffs fail to explain how the widespread media attention regarding the Infuse Device in 2008 and its off-label use and association with bone overgrowth (the very injury that Plaintiff suffered) escaped their attention after Scott Bell had to undergo corrective surgery in 2007. *Id.* ¶ 89 (discussing 2008 Wall Street Journal article titled "Medtronic Product Linked to Surgery Problems" which said that off-label applications were linked to "unwanted bone growth near nerves . . . that can lead to pain, repeat surgeries, and in some cases, emergency intervention."); *id.* ¶¶ 223-34 (alleging that in 2008, U.S. Senators Herb Kohl and Charles Grassley both sent letters to Medtronic regarding its alleged off-label marketing activities associated with the Infuse Device).

Court advises that Plaintiffs cannot add new parties or causes of action without a stipulation or an order of the Court.

IT IS SO ORDERED.

Dated: October 3, 2013

LUCY H. KOH
United States District Judge